PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

PART 177
PHARMACY PRACTICE AND DRUG CONTROL

333.17701 Meanings of words and phrases; general definitions and principles of construction.

Sec. 17701. (1) For purposes of this part the words and phrases defined in sections 17702 to 17709 have the meanings ascribed to them in those sections.

(2) In addition, article 1 contains general definitions and principles of construction applicable to all articles in this code and part 161 contains definitions applicable to this part.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Compiler's note: For transfer of powers and duties of certain health-related functions, boards, and commissions from the Department of Licensing and Regulation to the Department of Commerce, see E.R.O. No. 1991-9, compiled at MCL 338.3501 of the Michigan Compiled Laws.

Popular name: Act 368

333.17702 Definitions; A to C.

Sec. 17702. (1) "Agent" means an authorized person who acts on behalf of or at the discretion of a prescriber.

(2) "Brand name" means the registered trademark name given to a drug product by its manufacturer.

(3) "Current selling price" means the retail price for a prescription drug which is available for sale from a pharmacy.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 304, Eff. Mar. 31, 1987;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007.

Popular name: Act 368

333.17703 Definitions; D, E.

Sec. 17703. (1) "Device" means an instrument, apparatus, or contrivance, including its components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or to affect the structure or function of the body of human beings or other animals.

(2) "Dispense" means to issue 1 or more doses of a drug for subsequent administration to, or use by, a patient.

(3) "Dispensing prescriber" means a prescriber, other than a veterinarian, who dispenses prescription drugs.

(4) "Drug" means any of the following:

(a) A substance recognized or for which the standards or specifications are prescribed in the official compendium.

(b) A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.

(c) A substance, other than food, intended to affect the structure or a function of the body of human beings or other animals.

(d) A substance intended for use as a component of a substance specified in subdivision (a), (b), or (c), but not including a device or its components, parts, or accessories.

(5) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(6) "Electronically transmitted prescription" means the communication of an original prescription or refill authorization by electronic means including computer to computer, computer to facsimile machine, or electronic mail transmission that contains the same information it contained when the prescriber or authorized agent transmitted the prescription. Electronically transmitted prescription does not include a prescription or refill authorization transmitted by telephone or facsimile machine.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1980, Act 431, Eff. Mar. 31, 1981;—Am. 1992, Act 281, Imd. Eff. Dec. 18, 1992;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007.

Popular name: Act 368

333.17704 Definitions; F to I.

Sec. 17704. (1) “Federal act” means the federal food, drug, and cosmetic act of 1938, 21 U.S.C. 301 to

392.

(2) “Generic name” means the established or official name of a drug or drug product.

(3) “Harmful drug” means a drug intended for use by human beings which is harmful because of its toxicity, habit-forming nature, or other potential adverse effect, the method of its use, or the collateral measures necessary to its safe and effective use, and which is designated as harmful by the board according to rule.

(4) “Internship” means an educational program of professional and practical experience for an intern.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17705 Definitions; L.

Sec. 17705. (1) “Label” means a display of written, printed, or graphic matter on the immediate container of a drug or device, but does not include package liners. A requirement made by or under authority of this part that a word, statement, or other information appear on the label is not complied with unless the word, statement, or other information appears on the outside container or wrapper of the retail package of the drug or device as displayed for sale or is easily legible through an outside container or wrapper.

(2) “Labeling” means the labels and other written, printed, or graphic matter on a drug or device or its container or wrapper, or accompanying the drug or device.

(3) “License” in addition to the definition in section 16106 means a pharmacy license, drug control license, or a manufacturer or wholesale distributor of drugs or devices license.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 304, Eff. Mar. 31, 1987.

Popular name: Act 368

333.17706 Definitions; M, O.

Sec. 17706. (1) “Manufacturer” means a person who prepares, produces, derives, propagates, compounds, processes, packages, or repackages a drug or device salable on prescription only, or otherwise changes the container or the labeling of a drug or device salable on prescription only, and who supplies, distributes, sells, offers for sale, barters, or otherwise disposes of that drug or device and any other drug or device salable on prescription only, to another person for resale, compounding, or dispensing.

(2) “Official compendium” means the United States pharmacopoeia and national formulary, homeopathic pharmacopoeia of the United States, or a supplement thereof existing on July 1, 1983.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 304, Eff. Mar. 31, 1987.

Popular name: Act 368

333.17707 Definitions; P.

Sec. 17707. (1) “Personal charge” means the immediate physical presence of a pharmacist or dispensing prescriber.

(2) “Pharmacist” means an individual licensed under this article to engage in the practice of pharmacy.

(3) “Pharmacist intern” or “intern” means an individual who satisfactorily completes the requirements set forth in rules promulgated by the board and is licensed by the board for the purpose of obtaining instruction in the practice of pharmacy from a preceptor approved by the board.

(4) “Pharmacy” means a building or part of a building in which the practice of pharmacy is conducted.

(5) “Practice of pharmacy” means a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health. Professional functions associated with the practice of pharmacy include:

(a) The interpretation and evaluation of the prescription.

(b) Drug product selection.

(c) The compounding, dispensing, safe storage, and distribution of drugs and devices.

(d) The maintenance of legally required records.

(e) Advising the prescriber and the patient as required as to contents, therapeutic action, utilization, and possible adverse reactions or interactions of drugs.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1990, Act 333, Eff. Mar. 28, 1991.

Popular name: Act 368

333.17708 Definitions; P.

Sec. 17708. (1) "Preceptor" means a pharmacist approved by the board to direct the training of an intern in an approved pharmacy.

(2) "Prescriber" means a licensed dentist, a licensed doctor of medicine, a licensed doctor of osteopathic medicine and surgery, a licensed doctor of podiatric medicine and surgery, a licensed optometrist certified under part 174 to administer and prescribe therapeutic pharmaceutical agents, a licensed veterinarian, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery.

(3) "Prescription" means an order for a drug or device written and signed or transmitted by facsimile, electronic transmission, or other means of communication by a prescriber to be filled, compounded, or dispensed. Prescribing is limited to a prescriber. An order transmitted in other than written form shall be electronically recorded, printed, or written and immediately dated by the pharmacist, and that record constitutes the original prescription. In a health facility or agency licensed under article 17 or other medical institution, an order for a drug or device in the patient's chart constitutes for the purposes of this definition the original prescription. Subject to section 17751(2), prescription includes, but is not limited to, an order for a drug, not including a controlled substance as defined in section 7104 except under circumstances described in section 17763(e), written and signed or transmitted by facsimile, electronic transmission, or other means of communication by a physician prescriber licensed to practice in a state other than Michigan.

(4) "Prescription drug" means 1 or more of the following:

(a) A drug dispensed pursuant to a prescription.

(b) A drug bearing the federal legend "CAUTION: federal law prohibits dispensing without prescription" or "Rx only".

(c) A drug designated by the board as a drug that may only be dispensed pursuant to a prescription.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1994, Act 384, Eff. Mar 30, 1995;—Am. 1997, Act 153, Eff. Mar. 31, 1998;—Am. 2005, Act 85, Imd. Eff. July 19, 2005;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007;—Am. 2009, Act 150, Imd. Eff. Nov. 19, 2009.

Popular name: Act 368

333.17709 Definitions; S to W.

Sec. 17709. (1) "Sign" means to affix one's signature manually to a document or to use an electronic signature when transmitting a prescription electronically.

(2) "Substitute" means to dispense, without the prescriber's authorization, a different drug in place of the drug prescribed.

(3) "Wholesale distributor" means a person, other than a manufacturer, who supplies, distributes, sells, offers for sale, barters, or otherwise disposes of, to other persons for resale, compounding, or dispensing, a drug or device salable on prescription only that the distributor has not prepared, produced, derived, propagated, compounded, processed, packaged, or repackaged, or otherwise changed the container or the labeling thereof.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007.

Popular name: Act 368

333.17711 Practice of pharmacy; license or authorization required; use of words, titles, or letters.

Sec. 17711. (1) A person shall not engage in the practice of pharmacy unless licensed or otherwise authorized by this article.

(2) The following words, titles, or letters or a combination thereof, with or without qualifying words or phrases, are restricted in use only to those persons authorized under this part to use the terms and in a way prescribed in this part: "pharmacy", "pharmacist", "apothecary", "drugstore", "druggist", "medicine store", "prescriptions", and "r.ph.".

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2006, Act 390, Imd. Eff. Sept. 27, 2006.

Popular name: Act 368

333.17721 Michigan board of pharmacy; creation; membership; terms.

Sec. 17721. (1) The Michigan board of pharmacy is created in the department and shall consist of the following 11 voting members who shall meet the requirements of part 161: 6 pharmacists and 5 public members.

(2) The terms of office of the individual members of the board created under this section, except those appointed to fill vacancies, expire 4 years after appointment on June 30 of the year in which the term expires.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1993, Act 79, Eff. Apr. 1, 1994;—Am. 2006, Act 390, Imd. Eff. Sept. 27, 2006.

Popular name: Act 368

333.17722 Michigan board of pharmacy; duties generally.

Sec. 17722. In addition to the functions set forth in part 161, the board shall:

(a) Regulate, control, and inspect the character and standard of pharmacy practice and of drugs and devices manufactured, distributed, prescribed, dispensed, administered, or issued in this state and procure samples and limit or prevent the sale of drugs and devices that do not comply with this part.

(b) Prescribe minimum criteria for the use of professional and technical equipment and references in the compounding and dispensing of drugs and devices.

(c) Grant a pharmacy license for each separate place of practice in which the compounding or dispensing of prescription drugs or devices, or both, or the receiving of prescription orders in this state is to be conducted.

(d) Grant a drug control license for the place of practice of a dispensing prescriber who meets the requirements for the license.

(e) Grant a license to a manufacturer or a wholesale distributor of prescription drugs who meets the requirements for the license.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

Administrative rules: R 338.3971 et seq. of the Michigan Administrative Code.

333.17726 License; issuance.

Sec. 17726. The department shall issue a license to an applicant who is granted a license by the board.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17731 Renewal of license; evidence required; completion of hours or courses in pain and symptom management as continuing education; rules.

Sec. 17731. (1) Notwithstanding the requirements of part 161, the board may require a licensee seeking renewal of a pharmacist's license to furnish the board with satisfactory evidence that during the 2 years immediately preceding application for renewal the applicant has attended continuing education courses or programs, approved by the board, totaling not less than 30 hours or the satisfactory completion of a proficiency examination according to rules promulgated by the board.

(2) As required under section 16204, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the continuing education or proficiency examination requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 290, Imd. Eff. Dec. 22, 1986;—Am. 1994, Act 234, Imd. Eff. June 30, 1994.

Popular name: Act 368

Administrative rules: R 338.3041 et seq. of the Michigan Administrative Code.

333.17733 Relicensure of pharmacist; requirements.

Sec. 17733. A pharmacist who has not actively engaged in the practice of pharmacy for more than 3 consecutive years may be granted relicensure upon application and completion of a program of practical pharmacy experience of at least 200 hours, as determined by the board.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1981, Act 215, Imd. Eff. Jan. 5, 1982;—Am. 1988, Act 462, Eff. Sept. 1, 1989.

Popular name: Act 368

333.17737 Rules establishing standards for internship program; limited license required.

Sec. 17737. (1) The board shall promulgate rules to establish standards for an internship program and participation therein by interns and preceptors.

(2) An individual shall not engage in an internship program which includes the practice of pharmacy without a limited license under this part.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17741 Pharmacy license required; personal charge of pharmacy by pharmacist; responsibility for compliance with laws; control and personal charge of pharmacy services; effect of violation on pharmacy license.

Sec. 17741. (1) A pharmacy shall not be operated unless licensed by this part.

(2) A pharmacy open for business shall be under the personal charge of a pharmacist. A pharmacist shall not simultaneously have personal charge of more than 1 pharmacy. The person to whom a pharmacy license is issued and the pharmacists on duty are responsible for compliance with federal and state laws regulating the distribution of drugs and the practice of pharmacy. Pharmacy services shall be conducted under the control and personal charge of a pharmacist.

(3) A penalty for violation of this part does not affect the pharmacy license of other than the place of business where the violation occurred.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17742 Disclosure.

Sec. 17742. (1) The board may require an applicant or the holder of a pharmacy, manufacturer's, or wholesale distributor's license to fully disclose the identity of each partner, stockholder, officer, or member of the board of directors of the pharmacy, manufacturer, or wholesale distributor, as applicable.

(2) As used in this section and section 17768, "applicant" means a person applying for a pharmacy, manufacturer's, or wholesale distributor's license under this article. Applicant includes only 1 or more of the following:

(a) An individual, if the person applying is an individual.

(b) All partners, including limited partners, if the person applying is a partnership.

(c) All stockholders, officers, and members of the board of directors, if the person applying is a privately held corporation.

History: Add. 1987, Act 250, Imd. Eff. Dec. 28, 1987.

Popular name: Act 368

333.17743 Pharmacy license; contents; duration.

Sec. 17743. (1) A pharmacy license shall contain the name of the licensee, the address of the place of practice, a description of the pharmacy and the premises thereof, and other information the board requires.

(2) A pharmacy license is valid for 2 years, commencing on the date of issue and terminating on the date prescribed for pharmacists in section 16194.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17745 Drug control license; patient's chart or clinical record to include record of drugs dispensed; delegating authority to dispense drugs; storage of drugs; containers; labels; complimentary starter dose drug; information; compliance with MCL 333.7303a; inspection of locations; limitation on delegation; receipt of complimentary starter dose drugs by pharmacist; "complimentary starter dose" defined.

Sec. 17745. (1) Except as otherwise provided in this subsection, a prescriber who wishes to dispense prescription drugs shall obtain from the board a drug control license for each location in which the storage and dispensing of prescription drugs occur. A drug control license is not necessary if the dispensing occurs in the emergency department, emergency room, or trauma center of a hospital licensed under article 17 or if the dispensing involves only the issuance of complimentary starter dose drugs.

(2) A dispensing prescriber shall dispense prescription drugs only to his or her own patients.

(3) A dispensing prescriber shall include in a patient's chart or clinical record a complete record, including prescription drug names, dosages, and quantities, of all prescription drugs dispensed directly by the dispensing prescriber or indirectly under his or her delegatory authority. If prescription drugs are dispensed under the prescriber's delegatory authority, the delegatee who dispenses the prescription drugs shall initial the patient's chart, clinical record, or log of prescription drugs dispensed. In a patient's chart or clinical record, a dispensing prescriber shall distinguish between prescription drugs dispensed to the patient and prescription drugs prescribed for the patient. A dispensing prescriber shall retain information required under this subsection for not less than 5 years after the information is entered in the patient's chart or clinical record.

(4) A dispensing prescriber shall store prescription drugs under conditions that will maintain their stability, integrity, and effectiveness and will assure that the prescription drugs are free of contamination, deterioration, and adulteration.

(5) A dispensing prescriber shall store prescription drugs in a substantially constructed, securely lockable cabinet. Access to the cabinet shall be limited to individuals authorized to dispense prescription drugs in compliance with this part and article 7.

(6) Unless otherwise requested by a patient, a dispensing prescriber shall dispense a prescription drug in a

safety closure container that complies with the poison prevention packaging act of 1970, Public Law 91-601, 84 Stat. 1670.

(7) A dispensing prescriber shall dispense a drug in a container that bears a label containing all of the following information:

(a) The name and address of the location from which the prescription drug is dispensed.

(b) The patient's name and record number.

(c) The date the prescription drug was dispensed.

(d) The prescriber's name.

(e) The directions for use.

(f) The name and strength of the prescription drug.

(g) The quantity dispensed.

(h) The expiration date of the prescription drug or the statement required under section 17756.

(8) A dispensing prescriber who dispenses a complimentary starter dose drug to a patient shall give the patient at least all of the following information, either by dispensing the complimentary starter dose drug to the patient in a container that bears a label containing the information or by giving the patient a written document which may include, but is not limited to, a preprinted insert that comes with the complimentary starter dose drug, that contains the information:

(a) The name and strength of the complimentary starter dose drug.

(b) Directions for the patient's use of the complimentary starter dose drug.

(c) The expiration date of the complimentary starter dose drug or the statement required under section 17756.

(9) The information required under subsection (8) is in addition to, and does not supersede or modify, other state or federal law regulating the labeling of prescription drugs.

(10) In addition to meeting the requirements of this part, a dispensing prescriber who dispenses controlled substances shall comply with section 7303a.

(11) The board may periodically inspect locations from which prescription drugs are dispensed.

(12) The act, task, or function of dispensing prescription drugs shall be delegated only as provided in section 16215 and this part.

(13) A supervising physician may delegate in writing to a pharmacist practicing in a hospital pharmacy within a hospital licensed under article 17 the receipt of complimentary starter dose drugs other than controlled substances as defined by article 7 or federal law. When the delegated receipt of complimentary starter dose drugs occurs, both the pharmacist's name and the supervising physician's name shall be used, recorded, or otherwise indicated in connection with each receipt. A pharmacist described in this subsection may dispense a prescription for complimentary starter dose drugs written or transmitted by facsimile, electronic transmission, or other means of communication by a prescriber.

(14) As used in this section, "complimentary starter dose" means a prescription drug packaged, dispensed, and distributed in accordance with state and federal law that is provided to a dispensing prescriber free of charge by a manufacturer or distributor and dispensed free of charge by the dispensing prescriber to his or her patients.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1980, Act 431, Eff. Mar. 31, 1981;—Am. 1986, Act 304, Eff. Mar. 31, 1987;—Am. 1990, Act 333, Eff. Mar. 28, 1991;—Am. 1992, Act 281, Imd. Eff. Dec. 18, 1992;—Am. 1993, Act 305, Imd. Eff. Dec. 28, 1993;—Am. 1996, Act 355, Imd. Eff. July 1, 1996;—Am. 1997, Act 186, Eff. Mar. 31, 1998;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007.

Popular name: Act 368

333.17745a Definitions; individuals delegated authority to dispense prescriptions; delegating delivery of certain oral contraceptives; circumstances; delegating delivery of methadone.

Sec. 17745a. (1) As used in this section:

(a) “Medicaid” means the program of medical assistance established under title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396f, 1396g-1 to 1396r-6, and 1396r-8 to 1396v.

(b) “Medicare” means the federal medicare program established under title XVIII of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1395 to 1395b, 1395b-2, 1395b-6 to 1395b-7, 1395c to 1395i, 1395i-2 to 1395i-5, 1395j to 1395t, 1395u to 1395w, 1395w-2 to 1395w-4, 1395w-21 to 1395w-28, 1395x to 1395yy, and 1395bbb to 1395ggg.

(c) “Public health program” means 1 of the following:

(*i*) A local health department.

(*ii*) A migrant health center or a community health center as defined under sections 329 and 330 of subpart I of part C of title III of the public health service act, 42 U.S.C. 254b and 254c.

(*iii*) A family planning program designated by the family independence agency as a provider type 23 under

the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, and verified by the department of community health.

(*iv*) A methadone treatment program licensed under article 6.

(*v*) A rural health clinic.

(*vi*) A hospice rendering emergency care services in a patient's home as described in section 17746.

(d) "Rural health clinic" means a rural health clinic as defined in section 1861 of part C of title XVIII of the social security act, 42 U.S.C. 1395x, that is certified to participate in medicaid and medicare.

(2) Except as otherwise provided in subsections (3) and (4), in a public health program without an on-site pharmacy, a dispensing prescriber may delegate the dispensing of prescription drugs only to the following individuals:

(a) A registered professional nurse licensed under part 172.

(b) A physician's assistant licensed under part 170 or part 175, if the delegating dispensing prescriber is responsible for the clinical supervision of the physician's assistant.

(3) In a public health program without an on-site pharmacy, a dispensing prescriber may delegate the delivery of prescription drugs consisting only of prelabeled, prepackaged oral contraceptives under the following circumstances:

(a) The delivery is delegated to an appropriately trained individual.

(b) The delivery is performed pursuant to specific, written protocols.

(4) In a methadone treatment program licensed under article 6 without an on-site pharmacy, a dispensing prescriber may delegate the delivery of a prescription drug consisting only of 1 or more single doses of methadone, up to the maximum number of single doses allowed by law, to a registered client of the methadone treatment program, if all of the following requirements are met:

(a) The delivery is delegated to 1 of the following individuals:

(*i*) A registered professional nurse or a licensed practical nurse licensed under part 172.

(*ii*) A physician's assistant licensed under part 170 or part 175, but only if the delegating dispensing prescriber is responsible for the clinical supervision of the physician's assistant.

(b) The delivery is performed pursuant to specific, written protocols.

(c) The prescription drug described in this subsection is labeled in accordance with section 17745.

History: Add. 1993, Act 305, Imd. Eff. Dec. 28, 1993;—Am. 1999, Act 190, Imd. Eff. Nov. 24, 1999.

Popular name: Act 368

333.17745b Industrial clinic or prescriber practice without on-site pharmacy; dispensing prescription drug.

Sec. 17745b. (1) Subject to subsection (3), in an industrial clinic or other prescriber practice location without an on-site pharmacy, a dispensing prescriber may delegate the dispensing of prescription drugs only to the following individuals:

(a) A registered professional nurse licensed under part 172.

(b) A physician's assistant licensed under part 170 or part 175, if the dispensing prescriber is responsible for the clinical supervision of the physician's assistant.

(2) In an industrial clinic or other prescriber practice location without an on-site pharmacy, if a dispensing prescriber does not delegate the dispensing of a prescription drug, the dispensing prescriber shall do both of the following:

(a) Be physically present at the time the prescription drug is dispensed.

(b) Immediately before the prescription drug is dispensed, perform a final inspection of the type of prescription drug, labeling, dosage, and amount of the prescription drug dispensed.

(3) A dispensing prescriber who delegates the dispensing of a prescription drug to a patient in an industrial clinic or other prescriber practice location without an on-site pharmacy shall not delegate the dispensing of more than a 72-hour supply of the prescription drug.

(4) Before dispensing a prescription drug to a patient in an industrial clinic or other prescriber practice location without an on-site pharmacy, a dispensing prescriber who intends to charge for dispensing the drug shall give a written prescription to the patient and shall instruct the patient that he or she may elect to have the prescription filled by the dispensing prescriber or the patient's pharmacy of choice.

(5) If a dispensing prescriber intends to charge for dispensing a prescription drug to a patient in an industrial clinic or other prescriber practice location without an on-site pharmacy, the dispensing prescriber shall inform the patient of that fact before dispensing the prescription drug to the patient. The dispensing prescriber also shall list the charge for dispensing the prescription drug as a separate item on the patient's bill.

(6) This section does not apply to public health programs as defined in section 17745a.

History: Add. 1993, Act 306, Imd. Eff. Dec. 28, 1993.

Popular name: Act 368

333.17746 Hospice emergency care services in patients' homes; medication box exchange program.

Sec. 17746. A pharmacy may establish a medication box exchange program for hospice emergency care services rendered in patients' homes, pursuant to this section and rules promulgated under this section. The pharmacist in charge of the pharmacy shall be responsible for developing, implementing, and coordinating the program in conjunction with the medical director of the hospice program. The pharmacist in charge of the pharmacy shall be responsible for obtaining prescriptions from the hospice medical director for the drugs dispensed from a medication box. The board may promulgate rules to implement this section.

History: Add. 1993, Act 305, Imd. Eff. Dec. 28, 1993.

Popular name: Act 368

Administrative rules: R 338.471 et seq. of the Michigan Administrative Code.

333.17747 Drug control license; contents; duration; renewal; conditions; license as automatically void.

Sec. 17747. (1) A drug control license shall contain the name and address of the dispensing prescriber and each location in which the storage and dispensing of drugs occur and other information the board requires.

(2) A drug control license is valid until the date on which the dispensing prescriber's professional license must be renewed, at which time the drug control license shall be renewed. The drug control license shall be renewed automatically, if both of the following conditions are met:

(a) The dispensing prescriber indicates that he or she dispenses drugs and desires to continue to do so.

(b) The dispensing prescriber renews his or her professional license.

(3) A dispensing prescriber whose drug control license is renewed pursuant to subsection (2) is subject to section 16226 and the other requirements of this article and article 7.

(4) A drug control license is automatically void if a board suspends or revokes the licensee's health professional license.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1980, Act 431, Eff. Mar. 31, 1981;—Am. 1990, Act 333, Eff. Mar. 28, 1991;—Am. 1993, Act 79, Eff. Apr. 1, 1994.

Popular name: Act 368

333.17748 Pharmacy, manufacturer, or wholesale distributor of prescription drugs; license required; renewal; designation and responsibility of licensee.

Sec. 17748. A pharmacy, manufacturer, or wholesale distributor of prescription drugs, whether or not located in this state but doing business in this state, shall be licensed by the board in accordance with this part. Licenses shall be renewed biennially. A pharmacy, manufacturer, or wholesale distributor may designate an individual to be the licensee for the pharmacy, manufacturer, or wholesale distributor and the licensee is responsible for compliance with this part.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1978, Act 625, Imd. Eff. Jan. 6, 1979;—Am. 1988, Act 462, Eff. Sept. 1, 1989.

Popular name: Act 368

333.17749 Dispensing of diagnostic or therapeutic pharmaceutical agents by wholesale distributor or pharmacist to optometrist; condition; "therapeutic pharmaceutical agent" and "diagnostic pharmaceutical agent" defined.

Sec. 17749. (1) Notwithstanding any provision of this act or any rule promulgated under this act, a wholesale distributor or pharmacist may dispense a diagnostic pharmaceutical agent or a therapeutic pharmaceutical agent to a licensed optometrist for subsequent administration to optometric patients, if the optometrist provides the wholesale distributor or pharmacist with the number of the optometrist's certification of qualification to administer diagnostic pharmaceutical agents and the number of the optometrist's certification of qualification to administer and prescribe therapeutic pharmaceutical agents.

(2) As used in this section, "therapeutic pharmaceutical agent" and "diagnostic pharmaceutical agent" mean those terms as defined in section 17401.

History: Add. 1984, Act 42, Eff. Apr. 12, 1984;—Am. 1994, Act 384, Eff. Mar. 30, 1995.

Popular name: Act 368

333.17750 Person who distributes complimentary starter doses to prescribers; records; access by board; "complimentary starter dose" defined.

Sec. 17750. (1) A person who distributes complimentary starter doses to prescribers shall maintain records that include at least all of the following information:

(a) The name and address of the manufacturer distributing the complimentary starter doses.

(b) The name and address of each prescriber to whom complimentary starter doses were distributed.

(c) The type and amount of complimentary starter doses distributed to each prescriber.

(2) Upon request of the board, a person who distributes complimentary starter doses to prescribers shall provide the board access to the records required under subsection (1).

(3) As used in this section, "complimentary starter dose" means that term as defined in section 17745(1).

History: Add. 1990, Act 333, Eff. Mar. 28, 1991.

Popular name: Act 368

333.17750a Dispensing of prescription for therapeutic pharmaceutical agent by pharmacist.

Sec. 17750a. (1) A pharmacist may dispense a prescription for a therapeutic pharmaceutical agent issued by an optometrist certified by the Michigan board of optometry under part 174 as qualified to administer and prescribe therapeutic pharmaceutical agents.

(2) As used in this section, "therapeutic pharmaceutical agent" means that term as defined in section 17401.

History: Add. 1994, Act 384, Eff. Mar. 30, 1995.

Popular name: Act 368

333.17751 Dispensing prescription drug; requirements.

Sec. 17751. (1) A pharmacist shall not dispense a drug requiring a prescription under the federal act or a law of this state except under authority of an original prescription or an equivalent record of an original prescription approved by the board.

(2) A pharmacist may dispense a prescription written and signed or transmitted by facsimile, electronic transmission, or other means of communication by a physician prescriber in a state other than Michigan, but not including a prescription for a controlled substance as defined in section 7104 except under circumstances described in section 17763(e), only if the pharmacist in the exercise of his or her professional judgment determines all of the following:

(a) That the prescription was issued pursuant to an existing physician-patient relationship.

(b) That the prescription is authentic.

(c) That the prescribed drug is appropriate and necessary for the treatment of an acute, chronic, or recurrent condition.

(3) A pharmacist or a prescriber shall dispense a prescription only if the prescription falls within the scope of practice of the prescriber.

(4) A pharmacist shall not knowingly dispense a prescription after the death of the prescriber or patient.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1997, Act 153, Eff. Mar. 31, 1998;—Am. 2005, Act 85, Imd. Eff. July 19, 2005;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007.

Popular name: Act 368

333.17752 Prescription or equivalent record; preservation; disclosure; providing copies; refilling copy; applicability of subsection (3) to pharmacies sharing real-time, on-line database.

Sec. 17752. (1) A prescription, or an equivalent record of the prescription approved by the board, shall be preserved by a licensee or dispensing prescriber for not less than 5 years.

(2) A prescription or equivalent record on file in a pharmacy is not a public record. A person having custody of or access to prescriptions shall not disclose their contents or provide copies without the patient's authorization, to any person except to any of the following:

(a) The patient for whom the prescription was issued, or another pharmacist acting on behalf of the patient.

(b) The authorized prescriber who issued the prescription, or a licensed health professional who is currently treating the patient.

(c) An agency or agent of government responsible for the enforcement of laws relating to drugs and devices.

(d) A person authorized by a court order.

(e) A person engaged in research projects or studies with protocols approved by the board.

(3) A pharmacist may refill a copy of a prescription from another pharmacy if the original prescription has remaining authorized refills, and the copy is issued according to the following procedure:

(a) The pharmacist issuing a written or oral copy of a prescription shall cancel the original prescription and

record the cancellation. The record of cancellation shall include the date the copy was issued, to whom issued, and the identification of the pharmacist who issued the copy.

(b) The written or oral copy issued shall be a duplicate of the original prescription except that it shall also include the prescription number, the name of the pharmacy issuing the copy, the date the copy was issued, and the number of authorized refills remaining available to the patient.

(c) The pharmacist receiving a written or oral copy of the prescription shall exercise reasonable diligence to determine whether it is a valid copy, and having done so may treat the copy as an original prescription.

(d) Except as described in this part, all other copies furnished shall be used for information purposes only and clearly marked "for informational or reference purposes only".

(4) Subsection (3) does not apply to pharmacies that share a real-time, on-line database or other equivalent means of communication or to pharmacies that transfer prescriptions pursuant to a written contract for centralized prescription processing services as provided under section 17753.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2005, Act 73, Imd. Eff. July 19, 2005.

Popular name: Act 368

333.17753 Centralized prescription processing; conditions for performing or contracting; maintenance of policy and procedures manual; definition.

Sec. 17753. (1) A pharmacy may perform centralized prescription processing services or outsource those services to another pharmacy if each of the following conditions is satisfied:

(a) The pharmacies have the same owner or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state laws and regulations.

(b) The pharmacies share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to prepare a prescription drug order.

(c) The pharmacies comply with federal and state laws and regulations.

(2) A pharmacy that performs, or contracts for, centralized prescription processing services shall maintain a policy and procedures manual, along with documentation that implementation is occurring, and each shall be made available to the board for inspection and review upon request and the manual shall include, but is not limited to, a detailed description of how the pharmacies will do all of the following:

(a) Maintain appropriate records to identify the responsible pharmacist, or pharmacists, in the various stages of the drug product preparation, dispensing, and counseling process.

(b) Track the prescription drug order during each step in the drug product preparation, dispensing, and counseling process.

(c) Identify on the prescription label each pharmacy involved in the preparation and dispensing of the prescription drug order.

(d) Provide adequate security to protect the confidentiality and integrity of a patient's protected health information.

(e) Implement and maintain a quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(3) As used in this section, "centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, performing drug utilization review, completing claims adjudication, obtaining refill authorizations, initiating therapeutic interventions, and other functions related to the practice of pharmacy.

History: Add. 2005, Act 72, Imd. Eff. July 19, 2005.

Popular name: Act 368

333.17754 Electronic transmission of prescription; conditions; information; confidentiality; professional judgment as to accuracy, validity, and authenticity; original prescription.

Sec. 17754. (1) Except as otherwise provided under article 7 and the federal act, a prescription may be transmitted electronically as long as the prescription is transmitted in compliance with the health insurance portability and accountability act of 1996, Public Law 104-191, or regulations promulgated under that act, 45 CFR parts 160 and 164, by a prescriber or the prescriber's authorized agent and the data are not altered or modified in the transmission process. The electronically transmitted prescription shall include all of the following information:

(a) The name, address, and telephone number of the prescriber.

(b) The full name of the patient for whom the prescription is issued.

(c) An electronic signature or other identifier that specifically identifies and authenticates the prescriber or

the prescriber's authorized agent.

(d) The time and date of the transmission.

(e) The identity of the pharmacy intended to receive the transmission.

(f) Any other information required by the federal act or state law.

(2) The electronic equipment or system utilized in the transmission and communication of prescriptions shall provide adequate confidentiality safeguards and be maintained to protect patient confidentiality as required under any applicable federal and state law and to ensure against unauthorized access. The electronic transmission of a prescription shall be communicated in a retrievable, recognizable form acceptable to the intended recipient. The electronic form utilized in the transmission of a prescription shall not include "dispense as written" or "d.a.w." as the default setting.

(3) Prior to dispensing a prescription that is electronically transmitted, the pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription.

(4) An electronically transmitted prescription that meets the requirements of this section is the original prescription.

History: Add. 2006, Act 672, Imd. Eff. Jan. 10, 2007.

Popular name: Act 368

333.17755 Dispensing lower cost generically equivalent drug product; notice; contents of prescription label; passing on savings; restrictions; limitation on total charge.

Sec. 17755. (1) When a pharmacist receives a prescription for a brand name drug product, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product, the pharmacist shall dispense a lower cost but not higher cost generically equivalent drug product if available in the pharmacy, except as provided in subsection (3). If a drug is dispensed which is not the prescribed brand, the purchaser shall be notified and the prescription label shall indicate both the name of the brand prescribed and the name of the brand dispensed and designate each respectively. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed, except as otherwise provided in section 17756.

(2) If a pharmacist dispenses a generically equivalent drug product, the pharmacist shall pass on the savings in cost to the purchaser or to the third party payment source if the prescription purchase is covered by a third party pay contract. The savings in cost is the difference between the wholesale cost to the pharmacist of the 2 drug products.

(3) The pharmacist shall not dispense a generically equivalent drug product under subsection (1) if any of the following applies:

(a) The prescriber, in the case of a prescription in writing signed by the prescriber, writes in his or her own handwriting “dispense as written” or “d.a.w.” on the prescription.

(b) The prescriber, having preprinted on his or her prescription blanks the statement “another brand of a generically equivalent product, identical in dosage, form, and content of active ingredients, may be dispensed unless initialed d.a.w.”, writes in his or her own handwriting, the initials “d.a.w.” in a space, box, or square adjacent to the statement.

(c) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated.

(4) A pharmacist may not dispense a drug product with a total charge that exceeds the total charge of the drug product originally prescribed, unless agreed to by the purchaser.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17756 Label on prescription; contents.

Sec. 17756. (1) A prescription dispensed by a pharmacist shall bear upon the label the name of the medication in the container, unless the prescriber writes “do not label” on the prescription. The prescription shall also bear upon the label the following statement: “Discard this medication 1 year after the date it is dispensed.”, unless the medication expires on another date under applicable state or federal law or rules or regulations or other state or federal standards. If the medication expires on another date, the pharmacist dispensing the prescription shall strike or omit the statement required under this subsection and shall specify on the label the actual expiration date of the medication.

(2) A label on a prescription dispensed by a dispensing prescriber shall include the name of the medication in the container. The label shall also include the statement required under subsection (1) or the actual expiration date of the medication in the container in the same manner required under subsection (1) for a prescription dispensed by a pharmacist.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1993, Act 73, Eff. Jan. 1, 1994.

Popular name: Act 368

333.17757 Price information; notice; receipt evidencing transactions; omission; retention of copy of receipt; rules.

Sec. 17757. (1) Upon a request made in person or by telephone, a pharmacist engaged in the business of selling drugs at retail shall provide the current selling price of a drug dispensed by that pharmacy or comparative current selling prices of generic and brand name drugs dispensed by that pharmacy. The information shall be provided to the person making the request before a drug is dispensed to the person. A person who makes a request for price information under this subsection shall not be obligated to purchase the drug for which the price or comparative prices are requested.

(2) A pharmacist engaged in the business of selling drugs at retail shall conspicuously display the notice described in subsection (3) at each counter over which prescription drugs are dispensed.

(3) The notice required under subsection (2) shall be in substantially the following form:

NOTICE TO CONSUMERS
ABOUT PRESCRIPTION DRUGS

Under Michigan law, you have the right to find out the price of a prescription drug before the pharmacist fills the prescription. You are under no obligation to have the prescription filled here and may use this price information to shop around at other pharmacies. You may request price information in person or by telephone.

Every pharmacy has the current selling prices of both generic and brand name drugs dispensed by the pharmacy.

Ask your pharmacist if a lower-cost generic drug is available to fill your prescription. A generic drug contains the same medicine as a brand name drug and is a suitable substitute in most instances.

A generic drug may not be dispensed by your pharmacist if your doctor has written "dispense as written" or the initials "d.a.w." on the prescription.

If you have questions about the drugs which have been prescribed for you, ask your doctor or pharmacist for more information.

To avoid dangerous drug interactions, let your doctor and pharmacist know about any other medications you are taking. This is especially important if you have more than 1 doctor or have prescriptions filled at more than 1 pharmacy.

(4) The notice required under subsection (2) shall also contain the address and phone number of the board and the department. The text of the notice shall be in at least 32-point bold type and shall be printed on paper at least 11 inches by 17 inches in size. The notice may be printed on multiple pages.

(5) A copy of the notice required under subsection (2) shall be provided to each licensee by the department. Additional copies shall be available if needed from the department. A person may duplicate or reproduce the notice if the duplication or reproduction is a true copy of the notice as produced by the department, without any additions or deletions whatsoever.

(6) The pharmacist shall furnish to the purchaser of a prescription drug at the time the drug is delivered to the purchaser a receipt evidencing the transactions, which contains the following:

(a) The brand name of the drug, if applicable.

(b) The name of the manufacturer or the supplier of the drug, if the drug does not have a brand name.

(c) The strength of the drug, if significant.

(d) The quantity dispensed, if applicable.

(e) The name and address of the pharmacy.

(f) The serial number of the prescription.

(g) The date the prescription was originally dispensed.

(h) The name of the prescriber.

(i) The name of patient for whom the drug was prescribed.

(j) The price for which the drug was sold to the purchaser.

(7) Subsection (6)(a), (b), and (c) may be omitted by a pharmacist only if the omission is expressly required by the prescriber. The pharmacist shall retain a copy of each receipt for 90 days. The inclusion of subsection (6) on the prescription container label is a valid receipt to the purchaser. Including subsection (6) on the written prescription form and retaining the form constitutes retention of a copy of the receipt.

(8) The board may promulgate rules to implement this section.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 304, Eff. Mar. 31, 1987.

Popular name: Act 368

333.17757a Providing selling price of drugs dispensed upon request; notice to consumers about prescription drugs; contents; form; display; copies.

Sec. 17757a. (1) Upon a request made in person or by telephone, a dispensing prescriber engaged in the business of selling prescription drugs shall provide the current selling price of a drug dispensed by that dispensing prescriber or comparative current selling prices of generic and brand name drugs dispensed by that dispensing prescriber. The information shall be provided to the person making the request before a prescription drug is dispensed to the person. A person who makes a request for price information under this subsection is not obligated to purchase the prescription drug for which the price or comparative prices are requested.

(2) A dispensing prescriber engaged in the business of selling prescription drugs shall conspicuously display the notice described in subsection (3) in the location within the dispensing prescriber's practice where the dispensing occurs.

(3) The notice required under subsection (2) shall be in substantially the following form:

NOTICE TO CONSUMERS ABOUT PRESCRIPTION DRUGS

Under Michigan law, you have the right to find out the price of a prescription drug before the doctor provides a prescription drug directly to you. You are under no obligation to have the prescription filled here and may use this price information to shop around.

You may choose to have the prescription filled by your doctor or the pharmacy of your choice. Your doctor may not force you to have the prescription filled by the doctor. Your doctor cannot charge you for medications marked “sample.” Ask your doctor or pharmacist if a lower-cost generic drug is available to fill your prescription. A generic drug contains the same medicine as a brand name drug and is a suitable substitute in most cases. If you have questions about the drugs which have been prescribed for you, ask your doctor or pharmacist for more information. To avoid dangerous drug interactions, let your doctor and pharmacist know about any other medications you are taking. This is especially important if you have more than 1 doctor or have prescriptions filled at more than 1 location.

(4) The notice required under subsection (2) shall also contain the address and phone number of the board and the department. The text of the notice shall be in at least 32-point bold type and shall be printed on paper at least 11 inches by 17 inches in size. The notice may be printed on multiple pages.

(5) A copy of the notice required under subsection (2) shall be provided to each dispensing prescriber by the department. Additional copies shall be available if needed from the department. A person may duplicate or reproduce the notice if the duplication or reproduction is a true copy of the notice as produced by the department, without any additions or deletions.

History: Add. 1990, Act 333, Eff. Mar. 28, 1991;—Am. 1993, Act 305, Imd. Eff. Dec. 28, 1993.

Popular name: Act 368

333.17758 Repealed. 1986, Act 304, Eff. Mar. 31, 1987.

Compiler's note: The repealed section pertained to changing current selling price of drug and adjusting posted price.

Popular name: Act 368

333.17759 Dispensing harmful drug; requirements.

Sec. 17759. A harmful drug shall be dispensed only:

(a) As a prescription drug.

(b) Under the control of a licensed pharmacist or prescriber, who maintains records for the dispensing of these drugs which are the same as records required for the dispensing of prescriptions.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17761 Display of notice; dispensing prescription in safety closure container.

Sec. 17761. (1) A pharmacy, except for a pharmacy which only dispenses drugs for inpatient use at a health care facility, shall display the notice required under section 17757 in accordance with this part and the rules promulgated under this part.

(2) Unless otherwise requested by a patient, a prescription shall be dispensed in a safety closure container which complies with the definitions and the requirements of the poison prevention packaging act of 1970, 15 U.S.C. sections 1471 to 1476.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1980, Act 431, Eff. Mar. 31, 1981;—Am. 1986, Act 304, Eff. Mar. 31, 1987.

Popular name: Act 368

333.17762 Misbranded prescription.

Sec. 17762. (1) A prescription drug is considered misbranded unless the manufacturer's label states the name and place of business of the manufacturer of the finished dosage form of a drug and, if different, the name and place of business of the packer or distributor.

(2) As used in this section, "finished dosage form of a drug" means that form of the drug which is or is intended to be dispensed or administered to the patient and does not require further manufacturing or processing other than packaging or labeling, or both.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17763 Grounds for fine, reprimand, or probation; grounds for denying, limiting, suspending, or revoking license.

Sec. 17763. In addition to the grounds set forth in part 161, the disciplinary subcommittee may fine, reprimand, or place a pharmacist licensee on probation, or deny, limit, suspend, or revoke the license of a pharmacist or order restitution or community service for a violation or abetting in a violation of this part or rules promulgated under this part, or for 1 or more of the following grounds:

(a) Permitting the dispensing of prescriptions by an individual who is not a pharmacist, pharmacist intern, or dispensing prescriber.

(b) Permitting the dispensing of prescriptions by a pharmacist intern, except in the presence and under the personal charge of a pharmacist.

(c) Selling at auction drugs in bulk or in open packages unless the sale has been approved in accordance with rules of the board.

(d) Promoting a prescription drug to the public in any manner.

(e) In addition to the prohibition contained in section 7405(1)(e), dispensing a prescription for a controlled substance as defined in section 7104 that is written and signed or transmitted by facsimile, electronic transmission, or other means of communication by a physician prescriber in a state other than Michigan, unless the prescription is issued by a physician prescriber who is authorized under the laws of that state to practice medicine or osteopathic medicine and surgery and to prescribe controlled substances.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1993, Act 79, Eff. Apr. 1, 1994;—Am. 1997, Act 153, Eff. Mar. 31, 1998;—Am. 2004, Act 214, Eff. Oct. 12, 2004;—Am. 2004, Act 536, Imd. Eff. Jan. 3, 2005;—Am. 2005, Act 85, Imd. Eff. July 19, 2005;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007;—Am. 2009, Act 150, Imd. Eff. Nov. 19, 2009.

Popular name: Act 368

333.17764 Conduct constituting misdemeanor; violation; penalty; other violations.

Sec. 17764. (1) A person shall not sell, offer for sale, possess for sale, or manufacture for sale a drug or device bearing or accompanied by a label that is misleading as to the contents, uses, or purposes of the drug or device. A person who violates this subsection is guilty of a misdemeanor. In determining whether a label is misleading, consideration shall be given to the representations made or suggested by the statement, word, design, device, sound, or any combination thereof, and the extent to which the label fails to reveal facts material in view of the representations made or material as to consequences that may result from use of the drug or device to which the label relates under conditions of use prescribed in the label or under customary or usual conditions of use.

(2) A person shall not knowingly or recklessly do either of the following:

(a) Adulterate, misbrand, remove, or substitute a drug or device knowing or intending that the drug or device shall be used.

(b) Sell, offer for sale, possess for sale, cause to be sold, or manufacture for sale an adulterated or misbranded drug.

(3) Except as otherwise provided in this section, a person who violates subsection (2) is guilty of a felony punishable by imprisonment for not more than 2 years or a fine of not more than $1,000.00, or both.

(4) A person who violates subsection (2), which violation results in personal injury, is guilty of a felony punishable by imprisonment for not more than 4 years or a fine of not more than $4,000.00, or both.

(5) A person who violates subsection (2), which violation results in serious impairment of a body function, is guilty of a felony punishable by imprisonment for not more than 5 years or a fine of not more than $5,000.00, or both. As used in this subsection, "serious impairment of a body function" means that term as defined in section 58c of the Michigan vehicle code, 1949 PA 300, MCL 257.58c.

(6) A person who violates subsection (2), which violation results in death, is guilty of a felony punishable by imprisonment for not more than 15 years or a fine of not more than $20,000.00, or both.

(7) A person who violates subsection (2) with the intent to kill or to cause serious impairment of a body

function of 2 or more individuals, which violation results in death, is guilty of a felony punishable by imprisonment for life without the possibility of parole or life without the possibility of parole and a fine of not more than $40,000.00. It is not a defense to a charge under this subsection that the person did not intend to kill a specific individual, or did not intend to cause serious impairment of a body function of 2 or more specific individuals.

(8) This section does not prohibit an individual from being charged with, convicted of, or punished for any other violation of law that is committed by that individual while violating this section.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2004, Act 214, Eff. Oct. 12, 2004.

Popular name: Act 368

333.17765 Adulteration or misbranding; guaranty or undertaking as protection against penalties for violation; exception; notice to seller, manufacturer, or wholesale distributor.

Sec. 17765. A person is not subject to penalties for a violation of this part dealing with adulteration or misbranding, if the person establishes that a guaranty or undertaking was made in accordance with the federal act, or that a guaranty was signed by and contains the name and address of the person residing in this state from whom the former person received in good faith the drug or device, to the effect that the drug or device is not adulterated or misbranded within the meaning of this part. The guaranty does not protect the seller if the product is adulterated or misbranded under this part and the board has previously given written notice to the seller of that fact. The board shall not serve notice on the seller until the board has notified the manufacturer or wholesale distributor of the findings of the state analyst with reference to the product. The notice to the manufacturer or wholesale distributor shall be written and shall be mailed at least 10 days before a notice is given to a seller under this section.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17766 Additional conduct constituting misdemeanor.

Sec. 17766. Except as provided in sections 17766d and 17780, a person who does any of the following is guilty of a misdemeanor:

(a) Obtains or attempts to obtain a prescription drug by giving a false name to a pharmacist or other authorized seller, prescriber, or dispenser.

(b) Obtains or attempts to obtain a prescription drug by falsely representing that he or she is a lawful prescriber, dispenser, or licensee, or acting on behalf of a lawful prescriber, dispenser, or licensee.

(c) Falsely makes, utters, publishes, passes, alters, or forges a prescription.

(d) Knowingly possesses a false, forged, or altered prescription.

(e) Knowingly attempts to obtain, obtains, or possesses a drug by means of a prescription for other than a legitimate therapeutic purpose, or as a result of a false, forged, or altered prescription.

(f) Possesses or controls for the purpose of resale, or sells, offers to sell, dispenses, or gives away, a drug, pharmaceutical preparation, or chemical that has been dispensed on prescription and has left the control of a pharmacist.

(g) Possesses or controls for the purpose of resale, or sells, offers to sell, dispenses, or gives away, a drug, pharmaceutical preparation, or chemical that has been damaged by heat, smoke, fire, water, or other cause and is unfit for human or animal use.

(h) Prepares or permits the preparation of a prescription drug, except as delegated by a pharmacist.

(i) Sells a drug in bulk or in an open package at auction, unless the sale has been approved in accordance with rules of the board.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1990, Act 30, Eff. Mar. 28, 1991;—Am. 2004, Act 329, Imd. Eff. Sept. 23, 2004;—Am. 2006, Act 416, Imd. Eff. Sept. 29, 2006.

Popular name: Act 368

333.17766a Repealed. 2001, Act 236, Imd. Eff. Jan. 3, 2002.

Compiler's note: The repealed section pertained to use, possession, or delivery of androgenic anabolic steroid.

Popular name: Act 368

333.17766b Repealed. 2001, Act 231, Eff. Jan. 6, 2003.

Compiler's note: The repealed section pertained to recording prescription for androgenic anabolic steriod, methyltestosterone, testosterone, or fluoxymensterone.

Popular name: Act 368

333.17766c Possession of more than 12 grams of ephedrine or pseudoephedrine or mixture prohibited; violations; exceptions.

Sec. 17766c. (1) A person shall not possess more than 12 grams of ephedrine or pseudoephedrine alone or in a mixture.

(2) A person who violates this section is guilty of a felony punishable by imprisonment for not more than 2 years or a fine of not more than $2,000.00, or both.

(3) This section does not apply to any of the following:

(a) A person who possesses ephedrine or pseudoephedrine pursuant to a license issued by this state or the United States to manufacture, deliver, dispense, possess with intent to manufacture or deliver, or possess a controlled substance, prescription drug, or other drug.

(b) An individual who possesses ephedrine or pseudoephedrine pursuant to a prescription.

(c) A person who possesses ephedrine or pseudoephedrine for retail sale pursuant to a license issued under the general sales tax act, 1933 PA 167, MCL 205.51 to 205.78.

(d) A person who possesses ephedrine or pseudoephedrine in the course of his or her business of selling or transporting ephedrine or pseudoephedrine to a person described in subdivision (a) or (c).

(e) A person who, in the course of his or her business, stores ephedrine or pseudoephedrine for sale or distribution to a person described in subdivision (a), (c), or (d).

(f) Any product that the state board of pharmacy, upon application of a manufacturer, exempts from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine.

(g) Possession of any pediatric product primarily intended for administration to children under 12 years of age according to label instructions.

History: Add. 1994, Act 38, Eff. June 1, 1994;—Am. 2003, Act 308, Eff. Apr. 1, 2004.

Popular name: Act 368

333.17766d Pharmacy operated by department of corrections or under contract with county jail; resale or redistribution of prescription drug; definitions.

Sec. 17766d. (1) Notwithstanding section 17766(f), a pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail may accept for the purpose of resale or redispensing a prescription drug that has been dispensed and has left the control of the pharmacist if the prescription drug is being returned by a state correctional facility or a county jail that has a licensed physician's assistant, a registered professional nurse, or a licensed practical nurse, who is responsible for the security, handling, and administration of prescription drugs within that state correctional facility or county jail and if all of the following are met:

(a) The pharmacist is satisfied that the conditions under which the prescription drug has been delivered, stored, and handled before and during its return were such as to prevent damage, deterioration, or contamination that would adversely affect the identity, strength, quality, purity, stability, integrity, or effectiveness of the prescription drug.

(b) The pharmacist is satisfied that the prescription drug did not leave the control of the registered professional nurse or licensed practical nurse responsible for the security, handling, and administration of that prescription drug and that the prescription drug did not come into the physical possession of the individual for whom it was prescribed.

(c) The pharmacist is satisfied that the labeling and packaging of the prescription drug are accurate, have not been altered, defaced, or tampered with, and include the identity, strength, expiration date, and lot number of the prescription drug.

(d) The prescription drug was dispensed in a unit dose package or unit of issue package.

(2) A pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail shall not accept for return prescription drugs as provided under this section until the pharmacist in charge develops a written set of protocols for accepting, returning to stock, repackaging, labeling, and redispensing prescription drugs. The written protocols shall be maintained on the premises and shall be readily accessible to each pharmacist on duty. The written protocols shall include, at a minimum, each of the following:

(a) Methods to ensure that damage, deterioration, or contamination has not occurred during the delivery, handling, storage, and return of the prescription drugs which would adversely affect the identity, strength, quality, purity, stability, integrity, or effectiveness of those prescription drugs or otherwise render those drugs unfit for distribution.

(b) Methods for accepting, returning to stock, repackaging, labeling, and redispensing the prescription

drugs returned under this section.

(c) A uniform system of recording and tracking prescription drugs that are returned to stock, repackaged, labeled, and redistributed under this section.

(3) If the integrity of a prescription drug and its package is maintained, a prescription drug returned under this section shall be returned to stock and redistributed as follows:

(a) A prescription drug that was originally dispensed in the manufacturer's unit dose package or unit of issue package and is returned in that same package may be returned to stock, repackaged, and redispensed as needed.

(b) A prescription drug that is repackaged into a unit dose package or a unit of issue package by the pharmacy, dispensed, and returned to that pharmacy in that unit dose package or unit of issue package may be returned to stock, but it shall not be repackaged. A unit dose package or unit of issue package prepared by the pharmacist and returned to stock shall only be redispensed in that same unit dose package or unit of issue package and shall only be redispensed once. A pharmacist shall not add unit dose package drugs to a partially used unit of issue package.

(4) This section does not apply to any of the following:

(a) A controlled substance.

(b) A prescription drug that is dispensed as part of a customized patient medication package.

(c) A prescription drug that is not dispensed as a unit dose package or a unit of issue package.

(d) A prescription drug that is not properly labeled with the identity, strength, lot number, and expiration date.

(e) A prescription drug that is dispensed in a medical institution and returned to stock for redistribution in accordance with R 338.486 of the Michigan administrative code.

(5) As used in this section:

(a) “County jail” means a facility operated by a county for the physical detention and correction of persons charged with, or convicted of, criminal offenses or ordinance violations or persons found guilty of civil or criminal contempt.

(b) “Customized patient medication package” means a package that is prepared by a pharmacist for a specific patient that contains 2 or more prescribed solid oral dosage forms.

(c) “Repackage” means a process by which the pharmacy prepares a unit dose package, unit of issue package, or customized patient medication package for immediate dispensing pursuant to a current prescription.

(d) “State correctional facility” means a facility or institution that houses a prisoner population under the jurisdiction of the department of corrections.

(e) “Unit dose package” means a package that contains a single dose drug with the name, strength, control number, and expiration date of that drug on the label.

(f) “Unit of issue package” means a package that provides multiple doses of the same drug, but each drug is individually separated and includes the name, lot number, and expiration date.

History: Add. 2004, Act 329, Imd. Eff. Sept. 23, 2004.

Popular name: Act 368

333.17766e Sale of ephedrine or pseudoephedrine; requirements of retail distributor; exceptions; violation; fine; report.

Sec. 17766e. (1) Except as otherwise provided under this section, a person who possesses ephedrine or pseudoephedrine for retail sale pursuant to a license issued under the general sales tax act, 1933 PA 167, MCL 205.51 to 205.78, shall maintain all products that contain any compound, mixture, or preparation containing any detectable quantity of ephedrine or pseudoephedrine, a salt or optical isomer of ephedrine or pseudoephedrine, or a salt of an optical isomer of ephedrine or pseudoephedrine in accordance with 1 of the following:

(a) Behind a counter where the public is not permitted.

(b) Within a locked case so that a customer wanting access to the product must ask a store employee for assistance.

(c) Within 20 feet of a counter that allows the attendant to view the products in an unobstructed manner or utilize an antitheft device on those products that uses special package tags and detection alarms designed to prevent theft along with constant video surveillance as follows:

(*i*) The video camera is positioned so that individuals examining or removing those products are visible.

(*ii*) The video camera is programmed to record, at a minimum, a 1-second image every 5 seconds.

(*iii*) The video images must be maintained for a minimum of 6 months and made available to any law enforcement agency upon request.

(*iv*) The retailer shall prominently display a sign indicating that the area is under constant video surveillance in a conspicuous location, clearly visible to the public.

(2) If the products described under subsection (1) are maintained within 20 feet of a counter and that counter is not staffed by 1 or more employees at all times, then the retail distributor shall utilize antitheft devices and video surveillance as provided under subsection (1)(c) when the counter is not staffed. If all of the products described under subsection (1) are maintained behind the counter or within a locked case, then the retailer is not required to maintain a log or any other type of record detailing the sale of those products.

(3) A person who sells a product described in subsection (1) shall do each of the following:

(a) Require the purchaser of a product described under subsection (1) to produce a valid photo identification that includes the individual's name and date of birth.

(b) Except as otherwise provided under subsection (2), maintain a log or some type of record detailing the sale of a product described under subsection (1), including the date of the sale, the name and date of birth of the buyer, and the amount and description of the product sold. The log or other means of recording the sale as required under this subdivision shall be maintained for a minimum of 6 months and made available to only a law enforcement agency upon request. The log or other means of recording the sale is not a public record and is not subject to the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246. A person shall not sell or provide a copy of the log or other means of recording the sale to another for the purpose of surveys, marketing, or solicitations.

(4) This section does not apply to the following:

(a) A pediatric product primarily intended for administration to children under 12 years of age according to label instructions.

(b) A product containing pseudoephedrine that is in a liquid form if pseudoephedrine is not the only active ingredient.

(c) A product that the state board of pharmacy, upon application of a manufacturer or certification by the United States drug enforcement administration as inconvertible, exempts from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine.

(d) A product that is dispensed pursuant to a prescription.

(5) A person who violates this section is responsible for a state civil infraction as provided under chapter 88 of the revised judicature act of 1961, 1961 PA 236, MCL 600.8801 to 600.8835, and may be ordered to pay a civil fine of not more than $50.00 for each violation.

(6) By December 15, 2006, the department of state police shall submit a written report to the legislature regarding the impact and effectiveness of the amendatory act that added this section and section 17766f, including, but not limited to, the number of clandestine methamphetamine lab incidents before and after this legislation.

History: Add. 2005, Act 87, Eff. Dec. 15, 2005.

Popular name: Act 368

****** 333.17766f Subsections (1), (2), (3), (4), (5), (7), (8), and (9) take effect December 15, 2005: See 333.17766f(10) ******

333.17766f Possession of products containing ephedrine or pseudoephedrine; prohibited conduct; violation; penalty; sign; requirements; affirmative defense; rebuttal; conflict of local requirements with section; effective date of subsections (1) through (5) and (7) through (9).

Sec. 17766f. (1) A person who possesses products that contain any compound, mixture, or preparation containing any detectable quantity of ephedrine or pseudoephedrine, a salt or optical isomer of ephedrine or pseudoephedrine, or a salt of an optical isomer of ephedrine or pseudoephedrine for retail sale pursuant to a license issued under the general sales tax act, 1933 PA 167, MCL 205.51 to 205.78, shall not knowingly do any of the following:

(a) Sell any product described under this subsection to an individual under 18 years of age.

(b) Sell in a single over-the-counter sale more than 2 packages, or 48 tablets or capsules, of any product described under this subsection to any individual.

(c) Sell in a single over-the-counter sale more than 2 personal convenience packages containing 2 tablets or capsules each of any product described under this subsection to any individual.

(2) This section does not apply to the following:

(a) A pediatric product primarily intended for administration to children under 12 years of age according to label instructions.

(b) A product containing pseudoephedrine that is in a liquid form if pseudoephedrine is not the only active ingredient.

(c) A product that the state board of pharmacy, upon application of a manufacturer or certification by the United States drug enforcement administration as inconvertible, exempts from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine.

(d) A product that is dispensed pursuant to a prescription.

(3) A person who violates this section is responsible for a state civil infraction as provided under chapter 88 of the revised judicature act of 1961, 1961 PA 236, MCL 600.8801 to 600.8835, and may be ordered to pay a civil fine of not more than $50.00 for each violation.

(4) A person described under subsection (1) shall post, in a place close to the point of sale and conspicuous to both employees and customers, a sign produced by the department of community health that includes the following statement:

"The sale of any product that contains any compound, mixture, or preparation containing any detectable quantity of ephedrine or pseudoephedrine, a salt or optical isomer of ephedrine or pseudoephedrine, or a salt of an optical isomer of ephedrine or pseudoephedrine to a minor under 18 years of age is prohibited by law. In order to purchase a product described above, you must provide the retailer with an official Michigan operator's or chauffeur's license, an official Michigan personal identification card, or any other bona fide picture identification which establishes the identity and age of the individual. The retailer may require you to sign a log or other type of record detailing the sale of that product. State law further prohibits in a single over-the-counter transaction the sale of more than 2 packages, or 48 tablets or capsules, of any product described above.".

(5) If the sign required under subsection (4) is more than 6 feet from the point of sale, it shall be 5-1/2 inches by 8-1/2 inches and the statement required under subsection (4) shall be printed in 36-point boldfaced type. If the sign required under subsection (4) is 6 feet or less from the point of sale, it shall be 2 inches by 4 inches and the statement required under subsection (4) shall be printed in 20-point boldfaced type.

(6) The department of community health shall produce the sign required under subsection (4) and, beginning November 1, 2005, make the sign available to licensed retailers described in subsection (1) on the department's internet website free of charge. Licensed retailers described in subsection (1) shall obtain the sign from the department's internet website and provide copies of the sign free of charge, upon request, to persons who are subject to subsection (4).

(7) It is an affirmative defense to a citation issued pursuant to subsection (1)(a) that the defendant had in force at the time of the citation and continues to have in force a written policy for employees to prevent the sale of products that contain any compound, mixture, or preparation containing any detectable quantity of ephedrine or pseudoephedrine, a salt or optical isomer of ephedrine or pseudoephedrine, or a salt of an optical isomer of ephedrine or pseudoephedrine to persons under 18 years of age and that the defendant enforced and continues to enforce the policy. A defendant who proposes to offer evidence of the affirmative defense described in this subsection shall file and serve notice of the defense, in writing, upon the court and the prosecuting attorney. The notice shall be served not less than 14 days before the hearing date.

(8) A prosecuting attorney who proposes to offer testimony to rebut the affirmative defense described in subsection (7) shall file and serve a notice of rebuttal, in writing, upon the court and the defendant. The notice shall be served not less than 7 days before the hearing date and shall contain the name and address of each rebuttal witness.

(9) Notwithstanding any other provision of law, beginning December 15, 2005, a city, township, village, county, other local unit of government, or political subdivision of this state shall not impose any new requirement or prohibition pertaining to the sale of a product described under subsection (1) that is contrary to, or in any way conflicting with, this section. This subsection does not invalidate or otherwise restrict a requirement or prohibition described in this subsection existing on December 15, 2005.

(10) Subsections (1) through (5) and (7) through (9) take effect December 15, 2005.

History: Add. 2005, Act 86, Imd. Eff. July 20, 2005.

Popular name: Act 368

333.17767 Rules and determinations as to licensing.

Sec. 17767. The board may promulgate rules and make determinations necessary or appropriate to the licensing of pharmacists, drugs, dispensers, manufacturers, and wholesalers under this part.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1993, Act 79, Eff. Apr. 1, 1994.

Popular name: Act 368

Administrative rules: R 338.471 et seq. and R 338.3971 et seq. of the Michigan Administrative Code.

333.17768 Grounds for fine, reprimand, or probation, or for denying, limiting, suspending, or revoking license or ordering restitution or community service; applicability of subsection (2)(b).

Sec. 17768. (1) In a manner consistent with part 161, the disciplinary subcommittee may fine, reprimand, or place on probation, a person licensed under this part, or deny, limit, suspend, or revoke a person's license or order restitution or community service for a violation of this part or rules promulgated under this part.

(2) In addition to the grounds set forth in subsection (1), and in a manner consistent with part 161, the board may fine, reprimand, or place on probation a person licensed under this part, or deny, limit, suspend, or revoke a license issued under this part or order restitution or community service if the board finds that any of the following categories apply to an applicant or a partner, officer, or member of the board of directors of a pharmacy, manufacturer, or wholesale distributor licensed under this part or a stockholder of a pharmacy, manufacturer, or wholesale distributor which is a privately held corporation licensed under this part:

(a) The applicant or other person described in this subsection lacks good moral character.

(b) Subject to subsection (3), the applicant or other person described in this subsection has been convicted of a misdemeanor or a felony under a state or federal law relating to a controlled substance or the practice of pharmacy.

(c) The applicant or other person described in this subsection has furnished false or fraudulent material information or has knowingly omitted material information in an application filed under this part.

(d) The applicant or other person described in this subsection has previously maintained a financial interest in a pharmacy, manufacturer, or wholesale distributor which has been denied a license or federal registration, has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty.

(e) The applicant or other person described in this subsection is not in compliance with article 7 or the rules promulgated under article 7.

(3) Except for a conviction for a misdemeanor under section 7404 (2)(d) or a local ordinance that is substantially similar to section 7404 (2)(d), the reference to a misdemeanor in subsection (2)(b) applies only to a conviction for a misdemeanor that is directly related to the manufacture, delivery, possession, possession with intent to manufacture or deliver, use, distribution, prescription, or dispensing of a controlled substance. Subsection (2)(b) does not apply to a conviction for a misdemeanor based upon an unintentional error or omission involving a clerical or record-keeping function.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1987, Act 250, Imd. Eff. Dec. 28, 1987;—Am. 1993, Act 79, Eff. Apr. 1, 1994.

Popular name: Act 368

333.17770 Exceptions.

Sec. 17770. Except as to the labeling of poisonous or deleterious drugs and to adulterating, misbranding, and substituting, this part shall not apply:

(a) To the sale of paris green, white hellebore, and other insecticides.

(b) To the sale of any substance for use in the arts.

(c) To the retailing of non-narcotic, or nonprescription medicine or drug which is prepackaged, fully prepared by the manufacturer or producer for use by the consumer, and labeled in accordance with the requirements of the state and federal act.

(d) To the sale by merchants of ammonia, sulphur, any nonpoisonous flavoring essences or extracts, salt, bicarbonate of soda, or other prepackaged common household remedies or any food or food product which may also be found in any of the official compendiums and is not also considered as a poisonous, deleterious, or habit forming drug.

(e) To surgical or dental instruments and accessories, hearing aids, gases, oxygen tents, gas pressure reducing regulators, x-ray apparatus, therapeutic lamps, splints, and stethoscopes, and their component parts and accessories, or to equipment, instruments, apparatus, and contrivances used to render the articles effective in medical, surgical, or dental treatment; or to articles intended for external use.

(f) To articles or substances intended for generally recognized mechanical, agricultural, horticultural, or industrial consumption or use or photographic chemicals for home use.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17780 Cancer drug repository program.

Sec. 17780. (1) The board shall establish and maintain a cancer drug repository program that would allow

a person to donate a cancer drug or supply for use by an individual who meets the eligibility criteria specified under subsection (7). The board shall establish program guidelines, policies, and procedures addressing the cancer drug repository program. Under the cancer drug repository program, donations may be made on the premises of a health facility or pharmacy that elects to participate in the program and meets the requirements specified under subsection (2).

(2) Any health facility or pharmacy that is licensed and in compliance with all federal and state laws, rules, and regulations is eligible to participate in the cancer drug repository program. Participation in the cancer drug repository program is voluntary and a pharmacy or health facility may withdraw from participation in the cancer drug repository program at any time upon notification to the board. A notice to withdraw from participation may be given by telephone or regular mail. A pharmacy or health facility may choose to fully participate in the cancer drug repository program by accepting, storing, and dispensing or administering donated drugs and supplies or the pharmacy or health facility may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or health facility chooses to limit its participation, the pharmacy or health facility shall distribute any donated drugs to a fully participating cancer drug repository in accordance with subsection (8). A pharmacy or health facility that elects to participate in the cancer drug repository program shall submit the following information to the board in a form provided by the board that includes, at a minimum, each of the following:

(a) The name, street address, and telephone number of the pharmacy or health facility.

(b) The name and telephone number of a pharmacist who is employed by or under contract with the pharmacy or health facility, or other contact person who is familiar with the pharmacy's or health facility's participation in the cancer drug repository program.

(c) A statement indicating that the pharmacy or health facility is licensed in this state and in compliance with all federal and state laws, rules, and regulations and the chosen level of participation in the cancer drug repository program.

(3) An individual who is at least 18 years of age may donate legally obtained cancer drugs or supplies to a cancer drug repository. If the donated drugs have not been previously dispensed, a pharmacy, health facility, manufacturer, or wholesale distributor may also donate cancer drugs or supplies to a cancer drug repository. Donated drugs or supplies are acceptable for donation if they are determined to be eligible by a pharmacist who is employed by or under contract with a cancer drug repository as follows:

(a) A cancer drug is eligible for donation under the cancer drug repository program only if all of the following requirements are met:

(*i*) The donation is accompanied by a cancer drug repository donor form that is provided by the board and states that to the best of the donor's knowledge the donated drug has been properly stored and that the drug has never been opened, used, tampered with, adulterated, or misbranded. The board shall make the cancer drug repository donor form available on the board's website. The form shall be signed by the person making the donation or that person's authorized representative.

(*ii*) The drug's expiration date is at least 6 months later than the date the drug was donated.

(*iii*) The drug is in its original, unopened, tamper-evident unit dose packaging that includes the drug's lot number and expiration date. Single unit dose drugs may be accepted if the single unit dose packaging is unopened.

(*iv*) The drug is not adulterated or misbranded.

(b) Cancer supplies are eligible for donation under the cancer drug repository program only if all of the following requirements are met:

(*i*) The supplies are not adulterated or misbranded.

(*ii*) The supplies are in their original, unopened, sealed package.

(*iii*) The donation is accompanied by a cancer drug repository donor form that is provided by the board and states that to the best of the donor's knowledge the donated supply has been properly stored and that the supply has never been opened, used, tampered with, adulterated, or misbranded. The board shall make the cancer drug repository donor form available on the board's website. The form shall be signed by the person making the donation or that person's authorized representative.

(4) Controlled substances are not eligible for donation or acceptance under the cancer drug repository program. Cancer drugs and supplies that do not meet the criteria described under subsection (3) are not eligible for donation or acceptance under the cancer drug repository program. Cancer drugs and supplies may be donated on the premises of a cancer drug repository to a pharmacist designated by the repository. A drop box shall not be used to deliver or accept donations. Cancer drugs and supplies donated under the cancer drug repository program shall be stored in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with nondonated inventory.

(5) Cancer drugs and supplies that are donated under the cancer drug repository program shall be dispensed

by a pharmacist pursuant to a prescription by a prescriber or may be dispensed or administered by a dispensing prescriber. The cancer drugs and supplies shall be visually inspected by the pharmacist or dispensing prescriber before being dispensed or administered for adulteration, misbranding, and date of expiration. Cancer drugs or supplies that have expired or appear upon visual inspection to be adulterated, misbranded, or tampered with in any way may not be dispensed or administered.

(6) Before a cancer drug or supply may be dispensed or administered to an individual, the individual must provide verification that he or she has a current diagnosis of cancer, provide proof of his or her insurance, if any, and sign a cancer drug repository recipient form provided by the board acknowledging that the individual understands the information stated on the form. The form shall be made available to the public on the board's website. The form shall include, at a minimum, the following information:

(a) That the drug or supply being dispensed or administered has been donated and may have been previously dispensed.

(b) That a visual inspection has been conducted by the pharmacist or dispensing prescriber to ensure that the drug has not expired, has not been adulterated or misbranded, and is in its original, unopened packaging.

(c) That the pharmacist, the dispensing or administering prescriber, the cancer drug repository, the board, and any other participant of the cancer drug repository program cannot guarantee the safety of the drug or supply being dispensed or administered and that the pharmacist or prescriber has determined that the drug or supply is safe to dispense or administer based on the accuracy of the donor's form submitted with the donated drug or supply and the visual inspection required to be performed by the pharmacist or prescriber before dispensing or administering.

(7) Any resident of this state who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug repository program. Cancer drugs and supplies donated under the cancer drug repository program shall not be resold and shall only be dispensed or administered to residents of this state who are diagnosed with cancer. A pharmacist who dispenses those drugs and supplies donated under the cancer drug repository program shall not submit a claim or otherwise seek reimbursement from any public or private third party payer for drugs or supplies dispensed to any eligible individual in accordance with the program, nor shall a public or private third party payer be required to provide reimbursement for donated drugs or supplies dispensed by a pharmacist to an eligible individual in accordance with the program. Cancer drugs and supplies dispensed under the cancer drug repository program shall be dispensed in the following order of priority:

(a) Individuals who are uninsured or do not have insurance coverage for those cancer drugs or supplies.

(b) Individuals who are enrolled in medicaid, medicare, or any other public assistance health care program.

(c) All other individuals who are residents of this state and diagnosed with cancer.

(8) A cancer drug repository may charge the individual receiving a drug or supply a handling fee of not more than 250% of the medicaid dispensing fee or $5.00, whichever is less, for each cancer drug or supply dispensed or administered. Cancer drug repositories may distribute drugs and supplies donated under the cancer drug repository program to other repositories if requested by a participating repository. A cancer drug repository that has elected not to dispense donated drugs or supplies shall distribute any donated drugs and supplies to a participating repository upon request of the repository. If a cancer drug repository distributes drugs or supplies to another participating repository, the repository shall complete a cancer drug repository donor form provided by the board. The completed form and copy of the donor form that was completed by the original donor under subsection (3) shall be provided to the fully participating cancer drug repository at the time of distribution.

(9) Cancer drug repository donor and recipient forms shall be maintained for at least 5 years. A record of destruction of donated drugs and supplies that are not dispensed under subsection (7) shall be maintained by the dispensing repository for at least 5 years. For each drug or supply destroyed, the record shall include the following information:

(a) The date of destruction.

(b) The name, strength, and quantity of the cancer drug destroyed.

(c) The name of the person or firm that destroyed the drug.

(d) The source of the drugs or supplies destroyed.

(10) A manufacturer is not subject to criminal liability or liability in tort or other civil action for injury, death, or loss to a person or to property for any of the following causes of action:

(a) The intentional or unintentional adulteration or misbranding of the drug or supply by a party not under the control of the manufacturer.

(b) The failure of a party not under the control of the manufacturer to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

(c) Claims for payment to government or private payers.

(11) A health facility or pharmacy participating in the cancer drug repository program, a pharmacist dispensing a drug or supply pursuant to the program, a prescriber dispensing or administering a drug or supply pursuant to the program, or a donor of a cancer drug or supply is immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the cancer drug or supply is dispensed and no disciplinary action shall be taken against a pharmacist or prescriber as long as the drug or supply is donated, accepted, distributed, and dispensed according to the requirements of this section. This immunity does not apply if the act or omission involves reckless, wanton, or intentional misconduct, or malpractice unrelated to the quality of the cancer drug or supply.

(12) As used in this section:

(a) "Cancer drug" means a prescription drug that is used to treat either of the following:

(*i*) Cancer or the side effects of cancer.

(*ii*) The side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

(b) "Cancer drug repository" means a health facility or pharmacy that has notified the board of its election to participate in the cancer drug repository program.

(c) "Cancer supply" or "supplies" means prescription and nonprescription cancer supplies needed to administer a cancer drug.

(d) "Distribute" means to deliver, other than by administering or dispensing.

(e) "Donor" means an individual and not a manufacturer or wholesale distributor who donates a cancer drug or supply according to the requirements of the cancer drug repository program.

(f) "Health facility" means a facility licensed in accordance with article 17 as a county medical care facility, freestanding surgical outpatient facility, home for the aged, hospital, hospital long-term care unit, nursing home, and hospice.

(g) "Side effects of cancer" means symptoms of cancer.

(h) "Single unit dose packaging" means a single unit container for articles intended for administration as a single dose, direct from the container.

(i) "Tamper-evident unit dose packaging" means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.

History: Add. 2006, Act 416, Imd. Eff. Sept. 29, 2006.

Popular name: Act 368